K010402

March 9, 2001

MAR 1 4 2001

Special 510(k) Summary

1.0 Date

March 9, 2001

2.0 Submitter

Hudson Respiratory Care Inc.

3.0 Contact Person

Charles Mierkiewicz
Regulatory Affairs Specialist

4.0 Telephone

909-676-5611 ext. 1255

5.0 Proprietary Device Name

Circuits - Smooth-flo

6.0 Classification Name

Circuit- Breathing Circuit

7.0 Common Name

Circuit- Breathing Circuit

8.0 Predicate Device

Circuit

Predicate #1
Hudson RCI Universal Neonatal Ventilator Circuit
Model Number: 780-04
510(k) Number: K903083A

Predicate #2
Allegiance (Airlife) Infant respiratory Circuit Heated
Model Number: 1998-4H1
510(k) Number: K834570

[redacted]

[redacted]

Special 510 (k) Summary

9.0 Device Description

Circuit

The Hudson RCI circuits consist of a wye connector, which is attached to inspiratory and expiratory limbs. Air is channeled to the patient through the inspiratory circuit limb, which is heated by a 21-volt wire to maintain constant temperature. (Heated wire elements may be in one or both limbs of the circuit, depending on the circuit.) Inhaled air temperature is monitored at the patient connector or remote temperature port to assure that the inhaled air is at the proper temperature. Airway pressure is also monitored (by a heated humidifier) at the patient connector. Exhaled air is channeled away from the patient through the expiratory limb of the circuit, which may also contain either a water trap or heated wire element, (depending on the configuration of the circuit.) Some configurations will include a remote temperature port for patients placed in an isolette or radiant warmer. The Hudson RCI Cat. no. 780-40, 780-41, 780-42, 780-43 heated wire circuits are intended for use with the Hudson RCI ConchaTherm ® IV Heated Humidifier.

Special 510(k) Summary

10.0 Intended Use

Circuit

The Hudson RCI Cat. no. 780-40, 780-41, 780-42, 780-43 heated wire Circuits are non-sterile, 21-Volt, single patient use, heated wire circuits intended for use with neonatal, infant and pediatric patients in conventional (traditional) pressure.

There is no difference in intended use between the proposed Hudson RCI circuits and the predicate devices in that all of the devices are intended to convey humidified air to the patient's respiratory tract.

11.0 Patient Population

Circuit

Both the proposed Hudson RCI heated wire circuits and the predicate circuits are intended for use on pediatric, neonate, and infant populations.

12.0 Comparison of Technological Characteristics

The Hudson RCI Cat. no. 780-40, 780-41, 780-42, 780-43 heated wire circuits are substantially equivalent to the predicated devices, Nellcor N-501023, the Allegiance cat. no. 1998-4H1, and the Hudson RCI cat. no. 780-04 in design and function.

12.1 Materials

Circuit

The proposed Hudson RCI heated wire circuits Cat. no. 780-40, 780-41, 780-42, 780-43, are made of similar materials of construction as the predicate devices, (the Hudson RCI cat. no. 780-04, Allegiance 1998-4H1 and the Nellcor Puritan Bennet n-4501023 circuits,) and are common to those materials used in industry for ventilator circuits. The pressure monitoring ports on the proposed Hudson RCI circuits, the predicate Hudson RCI Cat. no. 780-04 circuit and the predicate Allegiance circuit, Cat. no. 1998-4H1, are all made of Polyvinyl Chloride. The inspiratory and expiratory limbs of the proposed Hudson RCI heated wire circuits and the Allegiance predicate device are both manufactured from smooth bore polyvinyl chloride. The water trap lid of the proposed Hudson RCI circuits and the Allegiance predicate device are both manufactured from Acrylic Plastic. The water trap jar for the proposed Hudson RCI circuits and the predicate Allegiance device are both manufactured from Polyethylene Plastic. The heated wires utilized in the proposed Hudson RCI heated wire circuits, the

predicate Hudson RCI Cat. no. 780-04, and the predicate Allegiance device, Cat. no. 1998-4H1, are all made from Polyvinyl Coated wire .

There is a difference between the materials used for the predicate Nellcor Cat. no. N-501023 circuit in that predicate inspiratory and expiratory limbs are made from a combination of Silicone Rubber, Polyester Elastomer and Polyvinyl Chloride, this is because the circuit is intended to withstand steam autoclave. The proposed Hudson RCI heated wire circuits, and the predicate Allegiance Cat. no. 1998-4H1 and the predicate Hudson RCI cat. no. 780-04 are not intended for steam autoclave.

12.1 Energy Source

Circuit

Neither the predicate devices or the Hudson RCI Cat. no. 780-40 series of heated wire circuits contain an energy source. All devices are used in conjunction with heated humidification systems.

12.3 Device Design

Circuit

The proposed Hudson RCI heated wire circuits and the predicate devices are similar in design in that they all are intended to connect to heated humidification systems, and ventilators, in order to convey humidified air to the patient's respiratory tract. The proposed Hudson RCI device and the predicates all have been designed with 10mm inspiratory limbs, and the proposed Hudson RCI heated wire circuits and the Allegiance predicate circuit utilize non corrugated, smooth bore PVC tubing for inspiratory and expiratory limbs. The Hudson RCI predicate cat. no. 780-04 differs in this respect in that it has been designed to utilize corrugated tubing. The proposed Hudson RCI circuits and all of the predicate devices utilize low flow dead space patient connectors to reduce back pressure. The proposed Hudson RCI device and all of the predicate devices also contain ISO 22mm female connections to the humidifier and ventilator, as well as ISO 15mm female connections to an artificial airway. The proposed Hudson RCI heated wire circuits, the predicate Hudson RCI cat.

no. 780-04 and the predicate Allegiance cat. no. 1998-4H1 are all designed for single patient use. However, the Nellcor predicate cat. no. N-501023 is designed to be steam autoclaved, hence the device is a reusable circuit.

12.3 Comparison of Technological Characteristics

Circuits

The Hudson RCI Cat. no. 780-40, 780-41, 780-42, 780-43, circuits are substantially equivalent to the predicate devices in design and function and intended use, in that all of the devices are intended to provide a conduit for the delivery and removal of humidified air to the patient. All of the devices were tested to the applicable standards listed below.

ISO 8185	Humidifiers for Medical use – General Requirements for Humidification Systems
ISO 5356-1	Anaesthetic and Respiratory Equipment – Conical Connectors-
ISO 5367	Breathing Tubes Intended For use with Anaesthetic Apparatus and Ventilators

Both the Hudson RCI proposed device and the predicate devices were tested for the following to determine their function:

1. Tubing must not kink at flows of 1.5 to 70 LPM at 37° C
2. Compressible volume with and without water trap.
3. Compatibility of pressure monitoring line with common ventilators.
4. Resistance to gas flow
5. Performance under conventional ventilation modes.

Testing to the requirements listed above demonstrated that the Hudson RCI Cat. no. 780-40, 780-41, 780-42, 780-43 heated wire circuits will function in all modes of neonatal ventilation. Both the predicates and the proposed Hudson RCI Cat no. 780-40 780-41, 780-42, 780-43 heated wire circuits are equipped with ISO 22mm and 15mm connections. All of the devices monitor proximal airway and temperatures to the patient and all devices exhibit low resistance to gas flow. Testing of the predicate devices and the proposed Hudson RCI heated wire circuits for resistance to gas flow and amplitude demonstrated that the proposed Hudson RCI device is equivalent to the predicate devices.

4.13 Conclusion

Based on the information contained in this 510(k) submission, Hudson RCI has determined that the proposed Hudson RCI Cat. 780-40, 780-41, 780-42, 780-43 heated wire circuits are substantially equivalent to their respective predicate devices listed in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2001

Mr. Charles Mierkiewicz
Hudson Respiratory Care, Inc.
27711 Diaz Road
P.O. Box 9020
Temecula. CA 92589-9020

Re: K010402
Smooth-Flo Circuit
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: February 12, 2001
Received: February 12, 2001

Dear Mr. Mierkiewicz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): K010402

Device Name: Smooth-flo Circuit

Indications for Use (Circuit):

This circuit provides a gas conduit from the ventilator to the patient and back to the ventilator, and includes both conventional and heated wire circuit modes of neonatal ventilation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010402

Prescription Use____X____ OR Over-the-Counter Use_____

Per 21 CFR 801.109

(Optional format 1-2-96)